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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,931	01/18/2002	Georges Nouadje	EGYP 3.0-018	1063
530	7590	07/01/2004	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			DIAMOND, ALAN D	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,931	NOUADJE ET AL.	
	Examiner	Art Unit	
	Alan Diamond	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03212002, 04152002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because at the fourth line, the term "an hydrophobic" should be changed to "a hydrophobic". Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claims 1 and 12 are objected to because of the following informalities: In claim 1, at line 5, the term "an hydrophobic" should be changed to "a hydrophobic". Claim 12 should start out with "12." Not "12.2". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9, 15, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, at lines 1-2, the term "said additive is selected from additive is selected from" needs to be corrected.

In claim 15, the term "of the order of" is indefinite because it is subjective.

In claim 26, at line 2, the term "- or tri-" should be changed to "di- or tri-".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 2-12059, herein referred to as JP '059.

JP '059 teaches an electrolyte composition comprising sodium octanesulphonate (i.e., instant additive) and phosphate buffer in water (i.e., instant support) (see the attached English abstract; and pages 2-3). The recitation “for capillary electrophoresis” is merely intended use and is not deemed to be a positive limitation of the instant claims. Since JP '059 teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

7. Claims 1-3, 7, 8, 12, 13, 16-19, 21, 23-25, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lauer et al, “Capillary Zone Electrophoresis of Proteins in Untreated Fused Silica Tubing,” Anal. Chem., Vol. 58, pages 166-170, (1986).

Lauer et al teaches a buffer system for capillary electrophoresis of a protein mixture, wherein the buffer system comprises, at pH 11, 20 mM CAPS buffer (which reads on both the instant buffer and additive, i.e., zwitterionic biological buffer), KCl, NaOH or HCl for adjusting pH, and water (which reads on the instant support) (see the experimental section at page 167; and Figure 1). The capillary tube is fused silica (see the title, abstract, and the experimental section at page 167). Since Lauer et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

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8. Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al, U.S. Patent 4,769,408.

Ogawa et al teaches a composition comprising phosphate buffer and sodium dodecylsulfate in a support (see Example 1 at cols. 15-16). The recitation "for capillary electrophoresis" is merely intended use and is not deemed to be a positive limitation of the instant claims. Since Ogawa et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

9. Claims 24-26 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellon et al, U.S. Patent 5,928,484.

Bellon et al teaches a buffer comprising Tris buffer (which reads on both the instant buffer system and the additive in claim 33), 1-hydroxy naphthalene 2-carboxylic acid (which reads on the additive in instant claims 24-26). In place of said 1-hydroxy naphthalene 2-carboxylic acid, there can be used sodium cholate, sodium dodecylbenzenesulfonate, sodium dodecylsulfate, naphthalene 2-carboxylic acid, or naphthalene 2-sulfonic acid (which each read on the additive in claims 24-26). Since Bellon et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

10. Claims 1-5, 7, 8, 12, 13, 16-19, 21, 23-25, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Keo et al, U.S. Patent 5,599,433.

Keo et al teaches the capillary zone electrophoresis (CZE) of glycosylated proteins in blood or plasma, wherein the buffer system contains, for example, 300 mM sodium borate (which reads on the instant buffer), 100 mM CAPS (which reads on the

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instant additive and zwitterionic biological buffer), and NaOH for adjusting the pH to 11 (see col. 3, lines 32-55; col. 4, lines 43-49; col. 5, line 16 through col. 6, line 27; and col. 8, lines 32-43). The capillary tube can be fused silica (see col. 8, lines 21-22). Since Keo et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

11. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Hjerten et al, U.S. Patent 5,938,930.

Hjerten et al teaches an electrolyte composition in a capillary tube, wherein the composition includes Tris buffer (which reads on the instant buffer) and octylphenoxypolyethoxyethanol (which reads on the instant additive) (see col. 3, lines 1-25). Since Hjerten et al teaches the limitations of the instant claim, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 24-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellon et al, U.S. Patent 5,928,484.

Bellon et al teaches a buffer comprising Tris buffer (which reads on both the instant buffer system and the additive in claim 33), 1-hydroxy naphthalene 2-carboxylic acid (which reads on the additive in instant claims 24-26). In place of said 1-hydroxy

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naphthalene 2-carboxylic acid, there can be used sodium cholate, sodium dodecylbenzenesulfonate, sodium dodecylsulfate, naphthalene 2-carboxylic acid, or naphthalene 2-sulfonic acid (which each read on the additive in claims 24-26). Said 1-hydroxy naphthalene 2-carboxylic acid, sodium cholate, sodium dodecylbenzenesulfonate, sodium dodecylsulfate, naphthalene 2-carboxylic acid, and naphthalene 2-sulfonic acid are examples of Bellon et al's molecules that have a hydrophobic moiety (see col. 6, lines 10-55). In general, said molecule having a hydrophobic moiety can, for example, comprise a linear or branched aliphatic chain of 3 to 10 carbon atoms bearing a sulfonic acid function. It is the Examiner's position that this encompasses C₆ to C₁₀ alkyl sulfonates, such as octanesulfonate. Bellon et al teaches the limitations of the instant claims other than the difference which is discussed below.

Bellon et al does not specifically teach that its molecule having a hydrophobic moiety can be a C₆ to C₁₀ alkyl sulfonates, such as octanesulfonate. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a C₆ to C₁₀ alkyl sulfonates, such as octanesulfonate for Bellon et al's molecule having a hydrophobic moiety because Bellon et al teaches that its molecule having a hydrophobic moiety can comprise a linear or branched aliphatic chain of 3 to 10 carbon atoms bearing a sulfonic acid function.

14. Claims 1-8, 12, 13, 16-21, 23-25, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauer et al, "Capillary Zone Electrophoresis of Proteins in

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Untreated Fused Silica Tubing," Anal. Chem., Vol. 58, pages 166-170, (1986) in view of Alter et al, U.S. Patent 5,753,094.

Lauer et al teaches a buffer system for capillary electrophoresis of a protein mixture, wherein the buffer system comprises, at pH 11, 20 mM CAPS buffer (which reads on both the instant buffer and additive, i.e., zwitterionic biological buffer), KCl, NaOH or HCl for adjusting pH, and water (which reads on the instant support) (see the experimental section at page 167; and Figure 1). The capillary tube is fused silica (see the title, abstract, and the experimental section at page 167). Lauer et al teaches the limitations of the instant claims other than the difference which is discussed below.

Lauer et al separates model proteins using said CZE (see Table I), but does not specifically teach the separation of the constituents of a sample such as blood, plasma, etc. Alter et al teaches that CZE permits the analysis and rapid and efficient separation of constituents of clinical samples, such as serum proteins, i.e., albumin, globulin, etc (see col. 1, line 56 through col. 2, line 13; and col. 6, lines 37-49). The clinical sample can be whole blood, serum, plasma, etc (see col. 1, lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used Lauer et al's CZE so as to analyze and separate clinical samples containing proteins because CZE permits the analysis and rapid and efficient separation of constituents of clinical samples, such as the separation of serum proteins, i.e., albumin, globulin, etc, as taught by Alter et al.

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15. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauer et al in view of Alter et al as applied to claims 1-8, 12, 13, 16-21, 23-25, and 33 above, and further in view of Ohmura et al, U.S. Patent 5,521,287.

Lauer et al in view of Alter et al, as relied upon for the reasons recited above, teaches the limitations of claim 22, the difference being that Lauer et al in view of Alter et al does not specifically teach the use of sodium sulfate in place of said KCl. Ohmura et al teaches that salts for adjusting ionic strength include KCl and sodium sulfate (see the paragraph bridging cols. 7 and 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the KCl in Lauer et al's buffer with sodium sulfate because the substitution of art recognized equivalent salts for adjusting ionic strength, as shown by Ohmura et al, would have been within the skill of an artisan.

16. Claims 24-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjerten et al, U.S. Patent 5,938,930.

Hjerten et al teaches an electrolyte composition in a capillary tube, wherein the composition includes Tris buffer (which reads on both the instant buffer and the zwitterionic buffer in claim 33) and octylphenoxypolyethoxyethanol (which reads on the instant additive) (see col. 3, lines 1-25). Said octylphenoxypolyethoxyethanol is an example of a surfactant that can be used in Hjerten et al's composition, and Hjerten et al is not limited to this particular surfactant (see col. 2, lines 15-30). Other surfactants that can be used include anionic surfactants such as sodium octanesulfonate, sodium

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decyl sulfate, etc (see col. 2, lines 15-30). Hjerten et al teaches the limitations of the instant claims other than the difference which is discussed below.

Hjerten et al does not provide an example where, for example, sodium octanesulfonate, sodium decyl sulfate is used as the surfactant in its composition. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used sodium octanesulfonate or sodium decyl sulfate as the surfactant in Hjerten et al's composition because such is clearly within the scope of Hjerten et al's disclosure.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/052,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 in said copending

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application teaches the use of octanesulphonate as an additive in the buffer for capillary electrophoresis

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Robert (US 2002/0195341) is hereby made of record.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753

Alan Diamond
June 28, 2004

A handwritten signature in black ink, appearing to read 'Alan Diamond', is written over the printed name and title.